

Message Text

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PAGE 01 BONN 08474 01 OF 02 271657Z

43

ACTION OES-05

INFO OCT-01 EUR-12 ISO-00 HEW-06 EB-07 COME-00 TRSE-00

PRS-01 CIAE-00 INR-07 NSAE-00 AID-05 /044 W

----- 076580

R 271642Z MAY 75

FM AMEMBASSY BONN

TO SECSTATE WASHDC 0367

UNCLAS SECTION 01 OF 02 BONN 08474

DEPT PASS OES FOR BEAUBIEN

E. O. 11652: N/A

TAGS: ETRD, TBIO, PINT, OTRA, GW

SUBJECT: US PHARMACEUTICAL REGULATION: STUDY TOUR OF
FRG PARLIAMENTARIANS

1. BEGIN SUMMARY: GROUP OF APPROXIMATELY 9 FRG
OFFICIALS, MOSTLY MEMBERS OF LOWER HOUSE OF
PARLIAMENT (BUNDESTAG) WHO BELONG TO THE SUB-
COMMITTEE DEALING WITH REGULATION OF PHARMACEUTICALS
WITHIN THE COMMITTEE ON YOUTH, FAMILY AND HEALTH,
WISH TO VISIT WASHINGTON AND ENVIRONS TO TALK TO FDA
OFFICIALS AND OTHERS IN REFERENCE TO CHANGES PROPOSED
TO FRG PHARMACEUTICAL CONTROL LEGISLATION.
DEPARTMENT'S ASSISTANCE REQUESTED IN ASCERTAINING
IF APPOINTMENTS AND MEETINGS COULD BE ARRANGED
DURING WEEK OF AUGUST 30 - SEPTEMBER 9, IN ACCORDANCE
WITH ITINERARY GIVEN BELOW. END SUMMARY

2. HERR REGIERUNGSDIREKTOR DIETER ADAM, THE
SECRETARY OF THE BUNDESTAG COMMITTEE ON YOUTH, FAMILY
AND HEALTH CALLED AT THE EMBASSY TO SEEK
ASSISTANCE IN DETERMINING IF APPOINTMENTS COULD BE
ARRANGED IN WASHINGTON AND VICINITY DURING THE PERIOD
FROM AUGUST 30 TO SEPTEMBER 9 WITH GOVERNMENTAL
AGENCIES AND OTHER ORGANIZATIONS KNOWLEDGEABLE IN
AREA OF CONTROL OF PHARMACEUTICALS IN ORDER TO GAIN
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PAGE 02 BONN 08474 01 OF 02 271657Z

INSIGHTS WHICH WILL BE USEFUL IN PARLIAMENTARY

EVALUATION OF DRAFT FRG
DRUG REFORM PRESENTLY BEFORE THE BUNDESTAG. (MEMBERS
OF THE SAME COMMITTEE MADE A STUDY TRIP TO
THE US IN JUNE 1974 TO REVIEW US FOOD LAW FOR THE SAME
PURPOSE.)

3. THE GROUP IS SLATED TO CONSIST OF SEVEN BUNDESTAG
DEPUTIES, ALL OF WHOM ARE MEMBERS OF THE SUB-
COMMITTEE, AN OFFICIAL OF THE MINISTRY FOR HEALTH,
YOUTH, AND FAMILY, AND HERR ADAM.

4. AN OUTLINE OF THE ITINERARY PROPOSED BY ADAM
FOLLOWS:

AUG. 30 (SAT.) LEAVE BONN IN THE EVENING FOR
WASHINGTON
AUG. 31 (SUN.) DAY FREE
SEPT. 1 (MON.) LABOR DAY HOLIDAY - DAY FREE
SEPT. 2 (TUES.) TO SEPT. 5 (FRIDAY) - MEETINGS WITH
APPROPRIATE OFFICIALS OF DEPT. HEALTH,
EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION
FEDERAL TRADE COMMISSION OR CONSUMER
PRODUCT SAFETY COMMISSION (WHICHEVER
MORE APPROPRIATE)
MEMBERS OF CONGRESS ALSO INVOLVED
IN QUESTION OF PHARMACEUTICALS
TWO OR THREE PHARMACEUTICAL FIRMS
(ON-SITE VISITS)
AMERICAN MEDICAL ASSOCIATION
RALPH NADER'S ORGANIZATION
SEPT. 6 (SAT.) FREE DAY
SEPT. 7 (SUN.) DEPARTURE FOR FRG
HOWEVER, IF IT IS NOT POSSIBLE TO FIT ALL THESE
APPOINTMENTS INTO A 4-WORKING DAY TIME FRAME, GROUP
WOULD BE WILLING TO DELAY DEPARTURE TO EVENING OF
SEPT. 9 (TUES.) AT LATEST, LEAVING SEPT 6 (SAT.) AND
SEPT. 7 (SUN.) FREE DAYS, AND SCHEDULING SEPT. 8 (MON.)
AND SEPT. 9 (TUES.) FOR APPOINTMENTS.

5. TOPICS OF INTEREST TO THE GROUP:
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PAGE 03 BONN 08474 01 OF 02 271657Z

LEGAL BASIS AND FUNDAMENTAL ORGANIZATION AND FUNCTION-
ING OF FDA, PARTICULARLY IN RESPECT TO PHARMACEUTICALS
AND FDA'S RELATION TO DHEW AND STATE REGULATORY
COMPETENCE
PHARMACEUTICAL REGISTRATION AND LICENSING
REQUIREMENTS
EXPERIENCE OF US IN SUCH AREAS AS BALANCING
GOVERNMENT INTEREST IN PROTECTING CONSUMING PUBLIC

AGAINST ADVERSE SIDE EFFECTS FROM DRUGS AND

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PAGE 01 BONN 08474 02 OF 02 271654Z

43

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R 271642Z MAY 75

FM AMEMBASSY BONN

TO SECSTATE WASHDC 0368

UNCLAS SECTION 02 OF 02 BONN 08474

INTEREST IN MAKING DRUGS AVAILABLE TO THE GENERAL
PUBLIC WHICH MAY HAVE SIDE EFFECTS FOR
A CERTAIN PERCENTAGE OF USERS.

US EXPERIENCE WITH ASPECTS OF DRUG TESTING SUCH AS
METHODS OF CLINICAL TESTING AND STATISTICAL
ANALYSES OF RESULTS (INCLUDING CHOICE OF
REPRESENTATIVE SAMPLE, TIME LIMITS), VALIDITY OF
ANIMAL TESTS, USE OF HUMAN SUBJECTS, LABELING OF
DRUGS TO INCLUDE DOSAGE, SIDE EFFECTS, ADVERTISING
OF DRUGS

PROBLEM OF "NATURAL MEDICINES"

6. IN ARRANGING VISITS TO PHARMACEUTICAL FIRMS, GROUP
WOULD BE WILLING TO TAKE A ONE-DAY TRIP OUTSIDE THE
WASHINGTON AREA. GROUP IS INTERESTED IN VISITING FIRMS
THAT HAVE HAD PROBLEMS BECAUSE OF GOVERNMENTAL
REGULATORY FUNCTIONS AS WELL AS THOSE WHICH HAVE NOT.

7. ACTION REQUESTED: EMBASSY REQUESTS DEPARTMENT
CONTACT DHEW, FDA, AND OTHER AGENCIES MENTIONED PARA 4
TO SEE IF THERE ARE ANY PROBLEMS WITH TIME FRAME
PROPOSED FOR VISIT. UPON RECEIPT OF DEPARTMENT'S
ANSWER HERR ADAM WILL CONTACT FONOFF TO BEGIN

MAKING ARRANGEMENTS FOR VISIT THROUGH FRG CHANNELS.
HILLENBRAND.

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Margaret P. Grafeld
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